



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2017-N-6538]

Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, to be Renamed Single-Use Internal Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify single-use female condoms, renaming the device to “single-use internal condom,” a postamendments class III device (product code MBU), into class II (special controls) subject to premarket notification (510(k)). FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. FDA is also proposing to amend the existing device identification for “female condom,” a preamendments class III device (product code OBY), by renaming the device “multiple-use female condom,” to distinguish it from the “single-use internal condom.” If finalized, this order will reclassify single-use female condoms from class III to class II and reduce regulatory burdens on industry as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome 510(k) before marketing their device.

DATES: Submit either electronic or written comments on the proposed order by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

Please see section IX of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal Rulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-N-6538 for “Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Monica Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G215, Silver Spring, MD 20993, 240-402-2791, monica.garcia@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section

513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as “preamendments devices”), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee) (the Panel); (2) published the Panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as “postamendments devices”) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. On July 9, 2012, Food and Drug Administration Safety and Innovation Act

(FDASIA) (Pub. L. 112-144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 513(e) provides that FDA may, by administrative order, reclassify a device based upon “new information.” The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at the time. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in “medical science” (*Upjohn Co. v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the “new information” to support reclassification under section 513(f)(3) must be “valid scientific evidence”, as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4)

of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

II. Device Description and Regulatory History

A single-use female condom is a sheath-like device that is inserted into the vagina prior to the initiation of coitus and discarded at its conclusion. It includes a mechanism (e.g., flexible rings) to hold the device in place during sexual intercourse. The device is a mechanical barrier that is intended to protect the user from sexually transmitted infections (STIs) and prevent pregnancy. The female condom is distinct from the male condom, which is a sheath that completely covers the penis, because it is inserted internally prior to intercourse. Based on the differences in technology, these devices have different failure modes and therefore have distinct classifications. Male condoms that completely cover the penis with a closely fitting membrane are regulated as class II devices under §§ 884.5300 and 884.5310 (21 CFR 884.5300 and 884.5310). A single-use female condom (product code MBU) is a postamendments device currently regulated as a class III device under section 513(f)(1) of the FD&C Act. FDA first learned of the device in January 1989, when FDA received a 510(k) from the Wisconsin Pharmacal Company, LLC (WPC). The device was intended to line the vaginal wall during sexual intercourse for purposes of contraception and STI prophylaxis. At that time, the device

was named the WPC-333 device but later renamed the Femshield/Reality Female Condom.

WPC purported in its 510(k) that the Reality Female Condom was substantially equivalent to the male condom identified in § 884.5300, as well as to a preamendments female condom known as the Gee Bee Ring. WPC provided documentation in the 510(k) that indicated the Gee Bee Ring was a pouch-like device designed to line the wall of the vagina during coitus for contraceptive (pregnancy prevention) and prophylactic (prevention of STI transmission) purposes. However, in contrast to the Reality Female Condom, the Gee Bee Ring was indicated for reuse (versus single-use) and was made using animal tissue (versus polyurethane).

Before receiving WPC's 510(k), FDA was unaware of the existence, commercial distribution, and use of the Gee Bee Ring as a female condom. FDA verified the preamendments status and uses of the Gee Bee Ring, and presented this information to the Obstetrics and Gynecology Devices Panel (referred to as the Classification Panel) on March 7, 1989. The Classification Panel reviewed all available information concerning the classification of a sheath-like device that is inserted into the vagina prior to coitus for purposes of contraception and STI prophylaxis. The Classification Panel recommended that FDA classify this generic type of device as distinct from the male condom identified in § 884.5300. The Classification Panel also recommended that this device be classified into class III, because no published laboratory or clinical study data could be found that would allow FDA to establish special controls for the device, and the device is purported or represented to be for a use which is of substantial importance in preventing impairment of human health. FDA agreed with the Classification Panel's recommended classification, and in the *Federal Register* of June 10, 1999 (64 FR 31164), FDA published a proposed rule to create a new classification regulation (§ 884.5330 (21 CFR 884.5330)) for the female condom and classify the device in class III. FDA finalized this

rule on May 18, 2000 (65 FR 31454). The Gee Bee Ring is the only female condom regulated under § 884.5330 and is identified using FDA product code OBY. In the *Federal Register* of August 25, 2010 (75 FR 52294), FDA published a proposed rule to require the filing, under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)), of a PMA or notice of completion of a product development protocol for any female condom that was in commercial distribution before May 28, 1976. FDA finalized this rule on August 16, 2011 (76 FR 50663) and noted that the Agency has no record of the Gee Bee Ring being marketed after it was classified in 2000.

In April 1989, FDA completed its review of WPC's 510(k) and determined that the Reality Female Condom was not substantially equivalent to either the male condom identified in § 884.5300 or the Gee Bee Ring. As a result, in accordance with section 513(f)(1) of the FD&C Act, the Reality Female Condom was automatically classified into class III. On May 7, 1993, FDA approved the PMA for the Reality Female Condom (P910064) and subsequently FDA identified this device type with the product code MBU (Ref. 1). On April 14, 1995, FDA approved the PMA for the Femidom Female Condom (P940033), which is identical to the Reality Female Condom. In this PMA, WPC authorized Chartex International plc to incorporate information contained in its approved PMA for the Reality Female Condom (Ref. 2). On January 8, 2008, FDA received a PMA (P080002) from the Female Health Company for the FC2 Female Condom and approved it on March 10, 2009 (Ref. 3). The FC2 Female Condom is a modified version of the Reality Female Condom. Since the introduction of the FC2 Female Condom, the Reality Female Condom has been referred to as the FC1 Female Condom. The FC2 Female Condom is a specific example of a single-use female condom that is the subject of this reclassification and is currently the only FDA-approved single-use female condom that is being marketed in the United States.

As part of the Center for Devices and Radiological Health's 2014-2015 strategic priority "Strike the Right Balance Between Premarket and Postmarket Data Collection," a retrospective review of class III devices subject to PMA was completed to determine whether or not, based on our current understanding of the technology, reclassification may be appropriate. On April 29, 2015, FDA published a notice in the *Federal Register* entitled "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection" in which FDA announced plans to consider reclassifying single-use female condoms identified with the MBU product code from class III to class II (80 FR 23798). Following this notice, FDA received seven comments, six of which supported reclassification of MBU. One comment did not support reclassification because it was stated that FDA lacked information to determine what risks might exist for female condoms of different design, materials, and manufacturing processes. FDA considered all comments in proceeding with this proposed order to reclassify single-use female condoms from class III to class II.

III. Proposed Reclassification and Summary of Reasons for Reclassification

FDA is proposing to reclassify single-use female condoms from class III into class II because sufficient information exists to establish special controls. FDA believes that these special controls, together with general controls, will provide a reasonable assurance of the device's safety and effectiveness for single-use female condoms.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II (special controls). FDA believes that there is sufficient information from nonclinical and clinical data submitted in PMA applications P910064 (Ref. 1), P940033 (Ref. 2), and P080002 (Ref. 3), available to FDA under section 520(h)(4) of the FD&C Act; postmarket experience; and peer-

reviewed literature (Refs. 4-7) to establish special controls that can effectively mitigate the risks to health of single-use female condoms that are identified in section IV. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA is also proposing to amend the existing device identification for female condom (§ 884.5330), a preamendments class III device, by renaming the device “multiple-use female condom” to better distinguish it from the “single-use female condom” that is the subject of this reclassification. One difference between the preamendments female condom (product code OBY) and the postamendments female condom (product code MBU) is that the preamendments female condom is indicated to be cleaned at the conclusion of coitus and reused. Additionally, a minor revision to the identification language is being proposed to change the term “diseases” to “infections” to use more appropriate clinical terminology. This proposed revision does not substantively change the meaning. It will remain a class III device, as FDA has neither received nor identified valid scientific evidence from nonclinical or clinical studies that demonstrate the safety and effectiveness of that type of female condom. Additionally, FDA is unaware of valid scientific evidence regarding the reuse of condoms (female or male) that could be used to establish special control(s) for a multiple-use female condom to provide a reasonable assurance of safety and effectiveness.

FDA is proposing to identify the single-use female condom that is the subject of this proposed order under the new name “single-use internal condom” to indicate that the new classification regulation includes the use of these devices inserted internally for vaginal and/or anal intercourse. This technology is distinct from that of male condoms, which completely cover the penis with a closely fitting membrane. This proposed classification does not include male

condoms that are class II devices regulated under §§ 884.5300 and 884.5310. FDA believes use of this device for vaginal and anal intercourse engender the same risks to health (with the exception of the risk of pregnancy when used for anal intercourse) and that the proposed special controls can effectively mitigate those risks when the device is used for these purposes.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA does not intend to exempt the proposed class II devices from 510(k) requirements. Persons who intend to market this type of device must submit to FDA a 510(k) and receive clearance prior to marketing the device.

IV. Risks to Health

After considering the information available to FDA from the recommendations of the Classification Panel for the classification of these devices (Refs. 8 and 9); data in PMA applications P910064, P940033, and P080002 available to FDA under section 520(h)(4) of the FD&C Act; postmarket experience; and peer-reviewed literature (Refs. 4-7), FDA determined that the probable risks to health associated with the use of single-use internal condoms are as follows:

- Pregnancy--Slippage, breakage, misdirection, or invagination of the device during vaginal intercourse could result in the occurrence of an undesired pregnancy.

- Transmission of infection--If the device fails due to slippage, breakage, misdirection, or invagination, contact with infected semen or vaginal secretions or vaginal/anal mucosa could result in the transmission of sexually-transmitted infections.
- Adverse tissue reaction--If the patient-contacting materials of the device are not biocompatible, local tissue irritation and sensitization, cytotoxicity, or system toxicity could occur when the device contacts the vagina, cervix, anus, and external male and female genitalia.
- Ulceration and other physical trauma--Use of the internal condom may cause abrasions, lacerations, bleeding, or other adverse effects to the vaginal, anal, or penile tissue if the device is not designed appropriately.

V. Summary of Data Upon Which the Reclassification Is Based

FDA has considered and analyzed the following information: the Manufacturer and User Facility Device Experience (MAUDE) database; data contained in PMAs approved 6 or more years before the date of this proposed order (reviewed under section 520(h)(4) of the FD&C Act, also known as the 6-year rule) (Ref. 10); the published literature; and the recommendations of the Classification Panel and FC1 and FC2 Panels.

Since 1993, the Center for Devices and Radiological Health (CDRH) has received one medical device report (MDR) regarding an adverse event associated with the use of an internal condom. This MDR reported injury following off-label use of the FC1 Female Condom during anal intercourse; the FC1 Female Condom is indicated for vaginal intercourse. Considering the number of internal condoms distributed in the United States since 1993 (approximately 3 to 4 million per year), the number of adverse events reported is low. FDA acknowledges that because internal condoms are over-the-counter devices, adverse events may be under reported.

Starting in 1989, several Panel meetings were held to discuss the safety and effectiveness of the internal condom. During the March 7, 1989, meeting, the Classification Panel recommended that the internal condom be classified into class III due to the absence of testing and clinical medical data regarding the safety and effectiveness of the device. On January 31 and December 10, 1992, the Obstetrics and Gynecology Devices Panel (referred to as the “FC1 Panel”) was convened to discuss the safety and effectiveness of the FC1 Female Condom and provide recommendations to FDA regarding a specific PMA application (P910064). During these meetings, the FC1 Panel discussed the available nonclinical and clinical data on the FC1 Female Condom, which included an acute failure modes study and contraceptive effectiveness study. On December 10, 1992, the FC1 Panel expressed concern regarding the high failure rates (21.7 percent rate of pregnancy in the Latin American population, 21.4 percent rate of pregnancy in U.S. women less than 25 years of age, 5.4 percent total clinical failure rate) of the FC1 Female Condom but recommended approval with conditions, which included labeling changes aimed at limiting the safety and effectiveness claims and the development of physician labeling. The FC1 Panel based this decision on the fact that no other barrier method existed for women to protect themselves against transmission of STIs if their partner would not use a male condom.

On January 8, 2008, FDA received a PMA (P080002) from the Female Health Company for the FC2 Female Condom (an updated version of the Reality Female Condom, now also referred to as the FC1 Female Condom), comprised of a nitrile sheath, nitrile outer ring, and polyurethane inner ring. Data provided in this PMA demonstrated that the FC2 Female Condom is an effective barrier to viral particles, is biocompatible, has acceptable mechanical properties, and has comparable rates of total clinical failure (2.18 percent) when compared to the FC1 Female Condom (2.92 percent). On December 11, 2008, CDRH convened the Obstetrics and

Gynecology Devices Panel (referred to as the “FC2 Panel”) in 2008 to discuss the safety and effectiveness of the FC2 Female Condom. The FC2 Panel recommended approval of the device with conditions, which included labeling changes aimed at improving consumer understanding of possible failure modes of the FC2 Female Condom and the outcomes of the acute failure modes study. The FC2 Panel found that the acute failure modes study comparing the FC2 Female Condom to the FC1 Female Condom provided a reasonable assurance of the safety and effectiveness for the FC2 Female Condom. Additionally, the FC2 Panel did not believe a contraceptive effectiveness study was needed to demonstrate reasonable assurance of safety and effectiveness because of the similarities in design between the FC2 and FC1 Female Condoms and the results of the acute failure modes study, which demonstrated comparable rates of clinical failure between the two female condoms. However, the FC2 Panel noted that the recommendation to not require a contraceptive effectiveness study applied only to the FC2 Female Condom and not other female condoms. As outlined in the proposed special controls in section VI, FDA has determined that a contraceptive effectiveness study is necessary to mitigate the risks to health related to pregnancy for this device type when used for vaginal intercourse.

A review of published literature evaluating the clinical use of the FC2 Female Condom indicates that clinical failure occurred in less than 5 percent of device uses (Refs. 4-7). Clinical failure is defined as the sum total of acute failure events for the internal condom. For the FC2 Female Condom, the acute failure events are slippage, breakage, misdirection, and invagination. This clinical failure rate may decrease with increased user experience with internal condoms (Ref. 5). The adverse events experienced by users of internal condom were infrequent and mild. The results of these published studies indicate that the FC2 Female Condom is effective and has a favorable safety profile. FDA identified no new risks or safety and effectiveness concerns

from the published literature that it did not previously identify through its review of the PMAs or either of the prior Obstetrics and Gynecology Devices Panel (“The Panel”) discussions of the female condom.

FDA acknowledges that the available valid scientific evidence, including the review of the MAUDE database, previous PMA approvals and The Panel discussions, and the published literature, primarily discuss use of internal condoms for vaginal intercourse. FDA believes that with the exception of pregnancy, the risks associated with internal condoms for vaginal intercourse are the same as those for anal intercourse (Refs. 11-13). Accordingly, FDA has tentatively determined that special controls can be established, in combination with general controls, which will provide reasonable assurance of the safety and effectiveness of internal condoms used for anal intercourse.

Based on its review of the FC1 and FC2 Female Condom PMAs; the discussions of the Classification Panel, FC1 Panel, and FC2 Panel on the safety and effectiveness of the internal condom; and peer-reviewed published literature, FDA has tentatively determined that available nonclinical and clinical performance data support that the risks associated with the internal condom are well understood and can be mitigated through special controls, including performance testing and labeling. FDA has also tentatively determined that the identified mitigation measures can be used to establish special controls, in addition to general controls, which are necessary to provide a reasonable assurance of safety and effectiveness for this device type. FDA believes that premarket notification and establishment of special controls will allow for assessment of the design and materials of single-use internal condoms through completion of a risk analysis, biocompatibility testing, mechanical performance testing, viral penetration

testing, and clinical performance testing and sufficient labeling. FDA, on its own initiative, is proposing to reclassify this postamendments class III device type into class II.

VI. Proposed Special Controls

FDA believes that the following special controls, together with general controls, address the risks to health and provide reasonable assurance of safety and effectiveness to mitigate the risks to health described in section V for the aforementioned single-use internal condoms.

The risks of pregnancy and STI are the most clinically significant risks of the single-use internal condom when used for vaginal and/or anal intercourse. Clinical testing is necessary to mitigate these risks to health. Clinical testing evaluates the rate of total clinical failure of the device and the rate of individual failure modes (slippage, breakage, misdirection, invagination, and other failure modes as appropriate) when the device is used as intended (i.e., during vaginal and/or anal intercourse). When the device is indicated for vaginal intercourse, clinical testing evaluates the cumulative pregnancy rate based on a contraceptive effectiveness study.

To mitigate the risk of STI due to contact with infected semen or vaginal secretions or vaginal/anal mucosa, FDA believes that a viral penetration study is needed to demonstrate that the device is an effective barrier to STIs.

In addition to clinical testing and viral penetration testing to mitigate the risks of pregnancy and STI, FDA believes that the device must demonstrate that it performs as intended under the anticipated conditions of use (i.e., vaginal and/or anal intercourse). Mechanical testing of the device must demonstrate that the device can withstand forces under anticipated use conditions by evaluation of the tensile, tear, and burst properties of the device. Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants. Furthermore, shelf-life testing must

demonstrate that the device maintains its performance characteristics and the packaging of the device maintains its integrity for the duration of the proposed shelf-life. The risk of an adverse tissue reaction due to the patient-contacting materials of the device is an additional risk of the single-use internal condom when used for vaginal and/or anal intercourse. In order to mitigate this risk, FDA believes the device must demonstrate biocompatibility.

FDA also believes that comprehensive labeling describing risks and mitigation measures associated with the single-use internal condom must be listed. When the device is indicated for vaginal intercourse, the labeling must include a contraceptive effectiveness table comparing typical use (actual use of the method, including inconsistent and incorrect use) and perfect use (when used correctly 100 percent of the time) pregnancy rates of the device to other available methods of birth control. The labeling must also list the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma. Because the physical properties of the device may be adversely affected by the use of personal lubricants, the labeling must specify whether the device is compatible with additional types of personal lubricants (e.g., water-based, silicone-based). Finally, the labeling must specify an expiration date to ensure that the device performs as intended over the stated shelf-life.

Table 1 shows how FDA believes that the risks to health identified in section IV can be mitigated by the proposed special controls. This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of single-use internal condoms.

Table 1.--Risks to Health and Mitigation Measures for Single-Use Internal Condoms

Identified Risks to Health	Mitigation Measures
Pregnancy	Contraceptive effectiveness study Acute failure modes study Nonclinical performance testing Shelf-life Labeling
Transmission of Infection	Acute failure modes study Viral penetration study Nonclinical performance testing Shelf-life Labeling
Adverse tissue reaction	Biocompatibility Labeling
Ulceration and other physical trauma	Acute failure modes study Nonclinical performance testing Shelf-life Labeling

VII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

IX. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 30 days after the date of its publication in the *Federal Register*.

X. References

The following references are on display in Dockets Management Staff (see ADDRESSES), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; most are available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. P910064 Summary of Safety and Effectiveness Data (SSED).
2. P940033 Premarket Approval Notice (60 FR 30310, June 8, 1995).
3. P080002 SSED is available on FDA's website at https://www.accessdata.fda.gov/cdrh_docs/pdf8/P080002B.pdf.
4. Joanis, C., M. Beksinska, C. Hart, et al., "Three New Female Condoms: Which Do South-African Women Prefer?" *Contraception*, 83(3):248-254, 2011.
5. Beksinska, M., J. Smit, C. Joanis, et al., "Practice Makes Perfect: Reduction in Female Condom Failures and User Problems With Short-Term Experience in a Randomized Trial." *Contraception*, 86(2):127-131, 2012.
6. Beksinska, M.E., G. Piaggio, J.A. Smit, et al., "Performance and Safety of the Second-Generation Female Condom (FC2) Versus the Woman's, the VA Worn-of-Women, and the Cupid Female Condoms: A Randomised Controlled Non-Inferiority Crossover Trial." *The Lancet Global Health*, 1(3):e146-152, 2013.

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9. The panel transcript and other meeting materials for the March 7, 1989, January 31, 1992, and December 10, 1992, Obstetrics and Gynecology Devices Panel.

10. “Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,” issued on August 9, 2000. Available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073709.pdf>.

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List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 884 be amended as follows:

PART 884--OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Amend § 884.5330 in Subpart F by revising the section heading and paragraph (a) to read as follows:

§ 884.5330 Multiple-use female condom.

(a) *Identification.* A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.

* * * * *

3. Add § 884.5340 in Subpart F to read as follows:

§ 884.5340 Single-use internal condom.

(a) *Identification.* A single-use internal condom is a sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the

conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (prevention of sexually transmitted infections) purposes.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate the following:

(i) Rate of clinical failure of the device and rate of individual failure modes of the device based on an acute failure modes study evaluating the intended use (vaginal and/or anal intercourse); and

(ii) Cumulative pregnancy rate when using the device based on a contraceptive effectiveness study (when the device is indicated for vaginal intercourse).

(2) Viral penetration testing must demonstrate the device is an effective barrier to sexually transmitted infections.

(3) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Mechanical testing must demonstrate the device can withstand forces under anticipated use conditions, include evaluation of tensile, tear, and burst properties of the device.

(ii) Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants.

(4) The device must be demonstrated to be biocompatible.

(5) Shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device must maintain integrity for the duration of the shelf-life.

(6) Labeling of the device must include:

(i) Contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma;

(iii) Expiration date; and

(iv) Statement regarding compatibility with additional types of personal lubricants.

Dated: November 28, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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